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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,499	07/25/2003	John A. Kink	OPHD-08311	3266

7590 03/07/2006

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EXAMINER	
XIE, XIAOZHEN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,499	KINK ET AL.	
	Examiner	Art Unit	
	Xiaozhen Xie	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Applicant's amendments of the specification filed on 25 July 2003, 6 August 2003 and 19 November 2004 have been entered in full. Applicant's amendment of the claims filed on 25 July 2003 is acknowledged.

Claims 1-58 have been cancelled. Claims 59-68 have been added. Claims 59-68 are pending and under examination. .

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 59, 60, 62, 64 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-4 of U.S. Patent No. 6,663,864 B1 in view of Eigler et al. (Immunol. Today, 1997, Oct., Vol. 18(10), pp. 487-92), and further in view of Woolley and Landon (J. Immunol. Methods, 1995, Vol. 178, pp. 253-265).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Here, claims 1-4 of U.S. Patent No. 6,663,864 B1 are directed to a method of treatment, comprising providing: a) a mammal, wherein said mammal is a human, having a symptom of inflammatory bowel disease selected from the group consisting of ulcerative colitis, proctitis, and Crohn's disease, b) a therapeutic enteric formulation comprising avian polyclonal antibodies directed to TNF, wherein said avian polyclonal antibodies are derived from chicken eggs; and administering orally said formulation to said mammal under conditions such that said symptom is reduced. The method of the

6,663,864 B1 patent differs from the method of the instant application in that the instant method comprising administering a therapeutic formulation comprising antibodies directed to TNF-α, which is purified from a chicken egg yolk. However, the claims of the 6,663,864 B1 patent recite purification of TNF antibodies from chicken eggs. Eigler et al. teach that successful use of anti-TNF antibody therapy (here referring TNF-α, pp. 487, line 3 in the 2nd paragraph) has been reported for patients with Crohn's disease (pp. 490, right column, 2nd paragraph). Woolley and Landon teach that hens confer passive immunity upon their offspring by transferring serum immunoglobins to their eggs, and the functional homologue of mammalian IgG, termed IgY, is passed into the developing yolk (pp. 254, left column, 3rd paragraph). Therefore, it would have been obvious to modify the method of claims 1-4 of the 6,663,864 B1 patent such that the antibodies are directed to TNF-α and purified from a chicken egg yolk. One having ordinary skill in the art would have been motivated to make such a modification for successful treatment of IBD, as per the teachings of Eigler et al., Woolley and Landon, and the claims of the 6,663,864 B1 patent.

Claims 59-65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-19 of U.S. Patent No. 6,395,273 B1 in view of Eigler et al., and further in view of Woolley and Landon.

Here, claims 1-19 of U.S. Patent No. 6,395,273 B1 are directed to a method of treatment, comprising providing: a) a mammal, a human, or a child with a symptom of inflammatory bowel disease (IBD), b) a therapeutic formulation comprising polyclonal antibodies directed to TNF, wherein said polyclonal antibodies are derived from chicken

eggs; and administering said formulation to the lumen of the intestine of said mammal, human or a child patient, and wherein said administering is performed orally or rectally, under conditions such that said symptom is reduced. The method of the 6,395,273 B1 patent differs from the method of the instant application in that the instant method comprising administering a therapeutic formulation comprising antibodies directed to TNF-α, which is purified from a chicken egg yolk. Eigler et al. teach that successful use of anti-TNF antibody therapy (here referring TNF-α, pp. 487, line 3 in the 2nd paragraph) has been reported for patients with Crohn's disease (pp. 490, right column, 2nd paragraph, note that Inflammatory Bowel Disease includes Crohn disease and Ulcerative Colotis, see Mesh definition). Woolley and Landon teach that hens confer passive immunity upon their offspring by transferring serum immunoglobins to their eggs, and the functional homologue of mammalian IgG, termed IgY, is passed into the developing yolk (pp. 254, left column, 3rd paragraph). Therefore, it would have been obvious to modify the method of claims 1-19 of the 6,395,273 B1 patent such that the antibodies are directed to TNF-α and purified from a chicken egg yolk. One having ordinary skill in the art would have been motivated to make such a modification for successful treatment of IBD, as per the teachings of Eigler et al., Woolley and Landon, and the claims of the 6,395,273 B1 patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolley and Landon, in view of Otto et al. (Clin. Diagn. Lab. Immunol., 1997, July, Vol. 4(4), pp. 487-90).

Woolley and Landon teach a method of preparing antibodies directed to human interleukin-6 (IL-6) from chicken egg yolk. Woolley and Landon detailed the procedure of purifying the anti-IL-6 antibodies from the egg yolk including collecting chicken eggs which comprise the antibody, separating egg yolk from egg white, and purifying the antibodies from the egg yolk comprising using PEG 6000 (pp. 255, in Materials and Methods section). Woolley and Landon, however, do not teach preparing antibodies directed to human TNF-α. Otto et al. teach that antibodies directed to feline TNF or the synthetic peptides based on the feline TNF sequence can be raised in chicken, and these antibodies specifically bind to a recombinant human TNF (pp. 487, Abstract and pp. 489, Table 2).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to modify the teachings of Woolley and Landon regarding purification of antibodies from chicken egg yolk by using the disclosure of Otto et al. to prepare antibodies directed to human TNF-α from chicken egg yolk. One of ordinary skill in the art would have been motivated to combine the teachings, because Woolley and Landon teach a method of preparing antibodies against IL-6, a closely related cytokine to TNF-α, from chicken egg yolk, and Otto et al. teach that chicken can

produce polyclonal antibodies directed to feline TNF, and that the resulting antibodies bind to human TNF. Therefore, the combined teachings provide a reasonable expectation of successfully making chicken egg yolk-derived anti-huTNF-α antibodies.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 59 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 is rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The independent claim is drawn to a method (of treatment) comprising administering to the lumen of the intestine of a human patient with symptoms of inflammatory bowel disease a therapeutic formulation comprising antibodies directed to TNF-α purified from chicken egg yolk. However, the steps set forth that delineate the method are not complete. There is no measurement step, and there is no step for the comparison of any results to a control. Thus, Claim 59 is indefinite in recitation as a method because the method does not clearly set forth method steps and there is an absence of a resolution step.

Claim Objections

Claims 59 and 64 are objected to because of the following informalities:

Claim 59 includes improper punctuation marks in line 1 " A method comprising;" and in line 2 "providing;", wherein semicolons should be colons.

Claim 64 is missing a period at the end of the sentence.

Appropriate correction is required.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph.D. can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Xiaozhen Xie, Ph. D.
February 27, 2006